

## **REMARKS**

Favorable reconsideration is respectfully requested in view of the foregoing amendments and the following remarks.

### **I. CLAIM STATUS AND AMENDMENTS**

Claims 39, 40, 42 and 48-50 were pending in this application when last examined.

Claims 1-38, 41 and 43-47 stood cancelled in this application when last examined.

Claims 39, 40, 42 and 48-50 were examined on the merits and stand rejected.

Claim 39 is amended herein to clarify the claimed invention. Support for this amendment may be found in paragraph [0016] on page 18 of the specification.

Claim 49 is cancelled herein without prejudice or disclaimer thereto.

No new matter has been added.

### **II. NOVELTY REJECTION**

Beginning on page 2 of the Office Action, claims 39-40, 42 and 48-50 are rejected under 35 USC 102(b) as anticipated by Kato et al. (US Pub. No. 2004/0022938; US Appl. No. 10/398,222).

The technical feature of current claim 39, is "...dispersing or dissolving one or more substance(s) selected from plasmids and siRNA and **an anionic polymer** in a liquid with lead particles, wherein the lead particles comprise a lipid assembly, liposome, an emulsion particle or a polymeric micelle..."

The Examiner stated that "Kato et al. clearly reads on the limitations of the claimed invention particularly to the extent that it discloses a method for producing coated complex particles, wherein the particle comprises a complex of a drug with **anionic lipid**, see ¶[0019], and further wherein said drug is a nucleic acid, see ¶[0021]."

Since the anionic polymer is different from anionic lipid, Applicants respectfully submit that the opinion of the Examiner is not correct.

On the other hand, the Examiner stated that "the method further comprises wherein the fine particles comprise a complex of a drug, liposome containing phospholipid and a dextran sulfate sodium salt, see ¶[0020]". It is known that dextran sulfate sodium salt is an **anionic polymer**.

However, Kato does not expressly teach the combination of a nucleic acid and an anionic polymer with liposome. Further, Kato does not disclose plasmids and siRNA.

Examples 15-19 and 24-27 in the specification of the application disclose that the invention is favorable for producing coated complex particles which comprise plasmids and siRNA.

Further, as for the preparations containing a dextran sulfate sodium salt (which is an **anionic polymer**) obtained in Examples 15 to 17, the recovery rates of EPC are roughly not lower than about 50%, which is high, and coating of the complex particles with the coating lipid is efficient; therefore, such are preferred to the preparation of Example 13 (without anionic polymer).

Reproduced below is the data in Table 4 from page 76 of the specification:

	Recovery rate (%)	
	Plasmid	EPC
Example 13 (without anionic polymer)	72.9	38.4
Example 15	74.7	68.4
Example 16	98.3	66.8
Example 17	64.5	47.1

For these reasons, Applicants respectfully submit that amended claim 39, and claims dependent thereon, are novel over Kato. Therefore, this rejection is untenable and should be withdrawn.

**CONCLUSION**

In view of the foregoing Amendments and Remarks, it is respectfully submitted that the present application is in condition for allowance and early notice to that effect is hereby requested.

If the Examiner has any comments or proposals for expediting prosecution, please contact the undersigned attorney at the telephone number below.

***The Commissioner is authorized to charge any deficiency or to credit any overpayment associated with this communication to Deposit Account No. 23-0975.***

Respectfully submitted,

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